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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

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April 15, 1998

E. EDWARD KAVANAUGH
PRESIDENT

Debra L. Bowen, M.D.
Director
Division of OTC Drug Evaluation (HFD-560)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

Dear Dr. Bowen:

This letter is to address several outstanding issues regarding FDA's Tentative Final Monograph for Sunscreen Drug Products. As you know, this is an extremely broad, comprehensive undertaking involving critical public health issues. On behalf of our members and the members of the joint CTFA/Nonprescription Drug Manufacturers Association Sunscreen Task Force, we wanted to stress the importance of communication between the Agency and the industry as FDA moves toward completion of final regulations for this product category.

Review of sunscreen drug products has been underway as part of the OTC Drug Review for approximately 25 years, a quarter of a century. In this time, the marketplace has changed dramatically. It has moved from a time when sunscreen protection was recommended only for occasional use at the beach -- and active ingredients and products were limited -- to the present when sunscreen protection is available in sophisticated formulations for the beach, sports activity, and everyday use. The products are available as pure sunscreens, or, increasingly, in cosmetic vehicles that are attractive to consumers and which provide cosmetic benefits as well as vehicles for the delivery of active ingredients.

Although FDA led the way in regulation of these products, the marketplace has become global and manufacturers now must contend with a variety of regulatory systems throughout the world. Harmonization of regulation has become an important goal.

During this quarter century, both medical knowledge about sun protection and consumer knowledge about the need for sun protection have moved light years ahead. Medical experts now know far more about the dangers of UV radiation and its relation to skin cancer, and far more about the importance of daily protection from a broad spectrum of UV radiation. Keeping pace with these developments, the industry has developed the capacity to formulate sunscreens that provide much greater UVB and

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UVA protection. Finally, consumer knowledge about the dangers of the sun and the need for sun protection has advanced so that consumers now know to seek out different types of products and different levels of protection depending on their work and life style.

It is critically important that, as FDA moves to complete work that was begun in a different era for this product category, it have a clear understanding of the industry and the needs of consumers for sunscreen products as it will exist at the beginning of the 21st Century. It is in this context that we hope you will consider the following issues and comments:

1. It is important that the meeting on sunscreen formulation originally scheduled for April 2 be rescheduled as soon as possible. This meeting was scheduled at the request of FDA staff, and was designed to provide an educational discussion of the technical issues and requirements of sunscreen formulation. This meeting has been under discussion with your staff for almost a year, and it was canceled with less than one week's notice. A great deal of effort and expense on the part of our membership went into the preparation of this presentation, and we believe it is an important element of FDA's ability to properly decide the complex issues presented by the Tentative Final Monograph. I am advised that a concern about this discussion was that it must be on the public record. Of course, we have no objection to a public meeting.

2. Because five years have passed since publication of the Tentative Final Monograph and four years have passed since filing of the CTFA/NDMA comments on the TFM, there are two issues on which we wish to modify our comments to take into account changes in the marketplace. Briefly, those two issues are the following

   a. We believe there should be no cap on SPF claims. Changing formulation technology allows the production of sunscreen products with increasingly higher SPFs. Previously, FDA proposed a cap of SPF 30 and CTFA argued that all SPF levels currently marketed (in 1994) should be allowed under the final monograph. There is widespread support in the medical community that any incremental increase in sun protection is beneficial. Increased protection is especially important for the more than 10 percent of the population that is photosensitive.

If any cap is placed on SPF claims at this time, it will ensure that products that provide greater protection will be prevented from being marketed, and eventually another lengthy process of amending the monograph will be necessary.

b. We believe the special labeling considerations proposed by CTFA for secondary sunscreens should extend to all such products regardless of SPF level. These special considerations included greater labeling flexibility and some limitations on claims that could be made for secondary sunscreens. We previously took the position that such considerations should be permitted only for a secondary sunscreen claiming an SPF of 6 or less, a recommendation that reflected the marketplace at that time when many of these products were in the SPF 6 or less category. Since then, most medical groups have stressed the importance of using a sunscreen product with an SPF of at least 15, whether for beach or everyday use. As those recommendations have increased, many more of the secondary sunscreen products in the market provide protection at a level of SPF 15 or higher. Since the purpose of CTFA's recommendation of labeling flexibility for secondary sunscreens was to eliminate labeling obstacles to making these products widely available, we now modify our comments to FDA on this issue.

A more detailed statement of our position on the above two issues will be filed with the docket and provided to you in the near future.

3. We stress that our urgent request to proceed with the meeting on sunscreen formulation highlights only the first of many issues on which we need to have a dialogue with FDA before a final regulation is decided upon. The following are the highest priority issues which our task force has identified as requiring further discussion:

    a. More flexible labeling. This includes a variety of issues designed to permit continued marketing of both primary and secondary sunscreens, and the fundamental need to ensure that this distinction between types of sunscreens is recognized in the final regulation. It also is essential that this category be assessed realistically in light of FDA's

proposed OTC labeling regulation, a proposal that was not considered when the Tentative Final Monograph was prepared. CTFA has asked that cosmetic drugs such as sunscreens be exempted from the OTC labeling proposal.

b. Broader use of term "sunblock" - This term should not be limited to products containing titanium dioxide, and should be permitted for all products meeting minimal sun protection requirements. We have suggested that some minimum threshold of sun protection such as SPF 12 be considered as a criteria for making a "sunblock" claim.

c. No minimum concentration of active ingredient(s) should be required. Active ingredient requirements should be based on performance testing.

4. Finally, we wish to note that the Congressional deadline of May, 1999 for promulgation of final regulations on sunscreen drug products contained in the FDA Modernization Act of 1997 does not require the promulgation of a complete final monograph. The Joint Explanatory Statement of the Conference Committee made clear that Congress did not expect FDA to complete action on all issues in the sunscreen monograph by May, 1999, stating that "(t)he conferees recognize that various technical and scientific issues may take longer to resolve than other aspects of the rulemaking. The conferees do not intend that all regulation in this area be complete or comprehensive by a specified date." (*Congressional Record*, November 9, 1997, H10476)

We stress this because the complexity of this subject matter, the changing marketplace and formulation technology, and the sheer number of issues to be decided require that the Agency take sufficient time to reach sound decisions with an adequate scientific and medical basis. There also is, as we have noted, the need for further dialogue with industry and the public. Therefore, we hope that you will resist any temptation to try and resolve every issue posed by the monograph, and identify only those on which there has been sufficient information and public dialogue for final resolution by May, 1999.

Thank you for your consideration of our views. This is a very important undertaking because of the key public health benefits of sunscreen products. Because of the diversity of these products, this rulemaking requires that the Agency be creative in setting requirements -- particularly labeling requirements for these products. Burdensome, "one formula fits all" requirements will only serve to remove the incentives to maintain or expand the availability of these products.

Our industry stands ready to assist you in any way possible to ensure that the broadest range of products providing sunscreen protection is available to the public. We encourage you to approach each issue under the monograph with the public health benefit of these products foremost in your mind.

I look forward to hearing from you regarding a schedule to resume our dialogue regarding this product category.

Respectfully submitted,

Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel

cc: Docket 78N-0038; Dockets Management Branch
Michael Weintraub, M.D. (HFD-105)
Donald Dobbs (HFD-560)
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